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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/731,678	12/08/2003	Benjamin Oshlack	02755/0205241-US0	4265

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EXAMINER	
SILVERMAN, ERIC E	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
03/11/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/731,678	OSHLACK ET AL.	
	Examiner	Art Unit	
	Eric E. Silverman, PhD	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80,81,83-86,88-93,97-102 and 104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *80,81,83-86,88-93,97-102 and 104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response and amendment, filed 1/9/2008, have been received. Claims 80, 81, 83 - 86, 88 - 93, 95, 97 - 102, and 104 are pending.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 80, 81, 83, 84, 88 - 91, 93, 95, 97 - 100, and 104 **remain** rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,126,684 to Robson et al, alone or as evidenced by US 3,758,680.

Claim 80 requires a composition of matter including an oxymorphone salt, a hydrophilic polymer, a binder, an alkylcellulose, and a diluent. The composition is said to "provide[s] a therapeutic effect for about 12 hours or more." This recitation is understood to be the intended use of the composition, and since the prior art composition is the same, it would be expected to be capable of performing the same intended use. In the alternative, this recitation is understood to be a property of the composition, wherein the same composition will by necessity have the same property. Claim 81 requires that the dosage form contains granules having a diameter between 0.1 mm and 3 mm. Claim 83 require that ethylcellulose is present as the alkylcellulose. Claim 84 requires a tablet, and claim 86 requires a matrix. Claim 88 requires that the

therapeutic effect be provided about 24 hours or more. This recitation is understood to be the intended use of the composition, and since the prior art composition is the same, it would be expected to be capable of performing the same intended use. In the alternative, this recitation is understood to be a property of the composition, wherein the same composition will by necessity have the same property. Claims 89 – 91 and are product by process claims which read on the products of claims 80 – 84. Claim 95 depends on claim 89, and requires that the alkylcellulose be ethylcellulose. Claim 97 is similar to claim 88. Claims 98 – 100 and 104 are methods of making the product by mixing the materials, granulating them, and incorporating the granules in a dosage form.

Robson teaches tablet dosage forms containing a PEG 6000 as a hydrophobic polymer, lactose as a diluent, and corn starch, talcum powder, and magnesium sterate as binders (Example 1). The powders are pressed through a screen with openings of 0.6 mm, thus there are granules present within the required range. The pressing through a screen reads on "subjecting to shear" in the method claims. In Example 2, the tablet is a matrix-tablet, containing an aqueous gelling matrix. Oxymorphone or a salt thereof is specifically suggested as a drug for use in these dosage forms (claim 2, note that this claim includes salts of all of the listed drugs). 10With regard to the timeframe this is understood to be a recitation of future intended use, because the claims require that the dosage form "provides" the therapeutic effect, said providing being a method of use step. In the alternative, if the timeframe is not mere statement of a future intended use and is afforded patentable weight (though such statements are clearly not to be afforded patentable weight), it is noted that the composition of Robson,

having the same components as that of instant claims, will by necessity have the same properties, such as duration of therapeutic effect.

Although it is not relied upon for the rejection US 3,758,680, which teaches that ethyl cellulose causes sustained release in pellets and granules when blended with active drugs (see example 5), is noted as evidence supporting the position that the compositions of Robson do indeed have the claimed properties.

Robson does not require the use of oxymorphone salt.

It would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to use oxymorphone in Robson. The motivation comes from Robson, who claims an embodiment of the invention where oxymorphone is used. Since this is a claimed embodiment, the artisan would enjoy a reasonable expectation of success.

Response to Arguments

Applicants' arguments have been fully considered, but are not persuasive. Applicants' first aver that the Office acknowledges that Robson does not specifically teach a composition that provides a therapeutic effect for 12 hours or more. This is not an accurate statement of the Office's position. The evidence of record clearly indicates that the composition of Robson, when the drug is oxymorphone salt, will indeed provide a therapeutic effect for at least about 12 hour or greater; the Office merely acknowledges that the reference itself does not mention this fact. It is noted that oxyporphone, even in an immediate release form, has a long half life, of about 8 hours (see oxymorphone disclosure, cited on PTO 892). As such, only a small amount of sustained release character would be required for the therapeutic effect to last for about

12 hours or more (note that the claims do not require release of drug over 12 hours), or for 24 hours or more. The evidence clearly indicates that alkylcelluloses, such as ethylcellulose, provide a sustained release character to drug release compositions. Given this evidence, combined with the fact that the composition of Robson has all of the same ingredients of instantly claimed composition and the fact that the drug has a very long half life, the weight of the evidence shows that the dosage form of Robson does indeed provide a therapeutic effect for the stated times.

Of course, the above discussion is only relevant if the claims' recitations of providing therapeutic release for a specified duration are afforded patentable weight. As discussed above, these recitations are in fact statements of future intended use of compositions, and since the prior art composition is the same, it would be expected to be capable of performing the same intended use, As such, Applicants' arguments referring to these recitations are not germane.

Applicants continue to argue that Robson does not exemplify a formulation containing oxymorphone salt. This argument is not well understood. The rejection at issue is one of obviousness, not anticipation. It is well established that a reference need not anticipate a claim to render the claim obvious. The fact that Robson does not exemplify the claimed drug is not in and of itself meaningful with respect to the obviousness analysis

Applicants then argue that there is no motivation to use oxymorphone salt instead of the exemplified drugs. In response, it is noted that oxymorphone and salts thereof are *claimed embodiments* of Robson's invention (claim 2). It cannot be said that

the use in place of an exemplified agent is, without more, non-obvious. That is especially true in this case, because Robson states that the examples "are not to be constructed as being limitations [of the invention]." Col. 4, lines 12 – 15.

Claims 83, 85, 92, 95, and 101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robson et al., as applied to claims , 81, 83, 84, 88 - 91, 93, 95, 97 - 100, and 104, above, and in further view of US 4,524,060 to Mughal et al for reasons of record.

Response to Arguments

Applicants argue that Mughal does not make up for the alleged deficiencies in Robson. These supposed deficiencies have been discussed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is (571)272-5549. The examiner can normally be reached on Monday to Thursday 7:00 am to 5:00 pm and Friday 7:00 am to noon.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571 272 0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

Eric E. Silverman, PhD
Art Unit 1618